

**Amendments to the Specification:**

In addition to the amendments to the specification and insertion of the Sequence Listing, which were requested by the Applicant in the Preliminary Amendment (a copy of which is submitted herewith), please amend the specification as follows:

Please replace the paragraph inserted (via the Preliminary Amendment) at page 1, line 5, with the following:

**--CROSS-REFERENCE TO RELATED APPLICATIONS**

This is a continuation application of U.S. Patent Application 09/736,659, filed 14 December 2000, which is a continuation-in-part of PCT application No. PCT/US00/10230, filed April 14, 2000, which claims the benefit of priority under 35 USC Section 119(e) of U.S. Provisional Patent Application No. 60/129,191, filed on April 14, 1999; U.S. Provisional Patent Application No. 60/180,353, filed on February 4, 2000; and U.S. Provisional Patent Application No. 60/193,556, filed on March 31, 2000, all of which are incorporated herein by reference.--

Please replace the paragraph inserted at page 7, line 21, with the following:

--Figure 5 is a graph showing the detection of DNA and white blood cells on FTA-NC membranes having a 1.2  $\mu$ m ~~mm~~ pore size using ELISA on the basis of antibodies to human DNA.--

Please replace the last two paragraphs on page 21, lines 23-31, with the following:

--DNA-positive and DNA-negative samples developed different color intensities on the FTA-nylon, and FTA-nitrocellulose membranes, both having a pore size of 0.2  $\mu\text{m}$ , when the result of the enzyme reaction was soluble products (table 1, Figure 3 ~~picture 1~~).

DNA-positive and DNA-negative samples only developed different color intensity, on FTA-nitrocellulose membrane, with a pore size of 0.2  $\mu\text{m}$ , when the result of the enzyme reaction was insoluble product (table 2, Figure 4 ~~picture 2~~).--

Please replace Example 7, paragraph 2 (see Preliminary Amendment), with the following:

--White blood cell concentration of 1 cell per microliter ( $\mu\text{l}$ ) ~~ml~~ represents the amount of cells allowed for a whole ~~Whole~~ blood unit, having a volume of 500 ml, to be marked as leukoreduced ~~leukoreduction~~ (LR) according to the European Standard. This method is able to detect such low levels of concentration that it ~~is~~ can be recommended for QC of leukoreduced blood.--

Please replace Example 7, paragraph 3 (see Preliminary Amendment), with the following:

--White blood cell suspensions were obtained from whole blood samples after lysing red blood cells with ammonium chloride buffer. The concentration of white blood cells can be in the range of 1 to 1000 cells per  $\mu\text{l}$ . In this experiment, 100  $\mu\text{l}$  ~~ml~~ of white blood cells from leukoreduced blood was loaded on FTA membrane and resulted in the collection of 600 pg DNA per well (note that there are ~~is~~ 6 pg of DNA in a single human cell). Fluorescent stain of cell nucleus with Propidium Iodine detergent solution and fluorescent microscopy were ~~was~~ used for validation of white blood cell lysis on the FTA membrane.--

Please replace Example 7, paragraph 5 (see Preliminary Amendment), with the following:

-- The detection limit was achieved by conducting an experiment when the same plate was loaded with genomic DNA samples in concentration range of 0.2 - 20 ng per well and white blood cell samples in amount of 90 - 360 per well. DNA samples were spotted on the membrane in volume of 2  $\mu$ l ~~ml~~ per well. White blood cell samples were loaded in volumes of 30 - 120  $\mu$ l ~~ml~~ per well by vacuum filtration.--

Please replace Example 7, paragraphs 7-9 (see Preliminary Amendment), with the following:

--The volume capacity for 0.8 -1.2 FTA-NC membrane was shown to be ~ 100  $\mu$ l ~~ml~~ of white blood cell suspension per well. So, it is possible to obtain 600 pg of DNA per well. This amount can be detected on FTA-NC membranes with ELISA using antibodies specific to human DNA above the background.

The sensitivity of the method, which causes the FTA membrane to lyse cells and capture of cell DNA and ELISA detection system on the basis of antibodies specific to human DNA is 0.2 ng of DNA per well in a 96 well plate format. In the initial experiments the sensitivity of the method was found as ~ 100  $\mu$ l ~~ml~~ per well of white blood cell suspension with cell concentration of 3 cells per  $\mu$ l ~~ml~~ (as average count), or 5 +/- 4 cells/ $\mu$ l ~~ml~~. Accuracy at this level is in the range of 5 +/- 4 cells per  $\mu$ l ~~ml~~. However, in an additional experiment, using the same method, the sensitivity was determined to be 33 cells per well.

With ELISA, on the basis of antibodies specific to human DNA, it was possible to see a difference between control wells loaded with PBS and DNA and white blood cell positive wells loaded with 0.2 ng DNA/well or 60  $\mu$ l ~~ml~~ white blood cells/well. There is a

linear dependency between color intensity of the assay and the amount of DNA. Additionally, there is a linear dependency between the assay and the white blood cells loaded per well. The data is presented in Figure 5.--

In the Table following paragraph 9 in Example 7 (see Preliminary Amendment), please replace ~~--mkl--~~ with ~~--μ--~~ as follows:

**Sensitivity of ELISA on the basis of antibodies Antibodies to human DNA for DNA determination and determination of white blood cells on FTA membranes**

<u>Control</u>	<u>DNA</u>	<u>DNA</u>	<u>DNA</u>	<u>30 <del>μl</del> <del>mkl</del> WBC</u>	<u>60 <del>μl</del> <del>mkl</del> WBC</u>	<u>120 <del>μl</del> <del>mkl</del> WBC</u>
	<u>0.2 ng</u>	<u>2.0 ng</u>	<u>20 ng</u>	<u>(3 cells/<del>μl</del> <del>mkl</del>)</u>	<u>(3 cells/<del>μl</del> <del>mkl</del>)</u>	<u>(3 cells/<del>μl</del> <del>mkl</del>)</u>
0	0.05	0.23	0.373	0.01	0.02	0.07
0.02	0.01	0.04	0.03	0.01	0.02	0.02